

IN THE CLAIMS:

1. Microparticles comprising: (a) a biodegradable polymer; (b) a cationic surfactant; and (c) a first polynucleotide-containing species adsorbed on the surface of the microparticles, wherein the adsorbed first polynucleotide-containing species constitutes at least 5 percent of the total weight of the microparticles.
2. The microparticles of claim 1, wherein the cationic surfactant comprises cetyltrimethylammonium bromide.
3. The microparticles of claim 1, wherein the microparticles have a diameter between 200 nanometers and 20 microns.
4. The microparticles of claim 1, wherein the polymer comprises a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, or a polycyanoacrylate.
5. The microparticles of claim 1, wherein the polymer comprises a poly(α -hydroxy acid).
6. The microparticles of claim 1, wherein the polymer comprises a poly(α -hydroxy acid) selected from poly(L-lactide), poly(D,L-lactide) and poly(lactide-co-glycolide).
7. The microparticles of claim 1, wherein the first polynucleotide-containing species is an immunological adjuvant.
8. The microparticles of claim 1, wherein the first polynucleotide-containing species comprises a CpG oligonucleotide or dsRNA.
9. The microparticles of claim 1, wherein the first polynucleotide-containing species encodes a polypeptide-containing antigen.
10. The microparticles of claim 1, wherein the first polynucleotide-containing species is a vector construct that encodes a polypeptide-containing antigen.

11. The microparticles of claim 10, wherein the vector construct is an RNA vector construct.
12. The microparticles of claim 10, wherein the vector construct is a DNA vector construct.
13. The microparticles of claim 12, wherein the DNA vector construct is a plasmid.
14. The microparticles of claim 12, wherein the DNA vector construct is a RNA-virus-based plasmid.
15. The microparticles of claim 9, wherein the polypeptide-containing antigen is derived from a pathogenic organism.
16. The microparticles of claim 15, wherein the pathogenic organism is selected from a virus, a bacterium, a fungus and a parasite.
17. The microparticles of claim 15, wherein the pathogenic organism is selected from HIV, hepatitis B virus, hepatitis C virus, meningitis B, *Haemophilus influenza* type B, pertussis, diphtheria, tetanus, and influenza A virus.
18. The microparticles of claim 9, wherein the polypeptide-containing antigen is derived from HIV gp120, HIV gp140, HIV gp160, HIV p24gag or HIV p55gag.
19. The microparticles of claim 1, further comprising a species entrapped within the microparticles, wherein the entrapped species is selected from an entrapped polynucleotide-containing species, an entrapped polypeptide-containing species, an entrapped polysaccharide-containing species, an entrapped hormone, an entrapped enzyme, and an entrapped immunological adjuvant.

20. The microparticles of claim 19, wherein the entrapped species is an entrapped polypeptide-containing antigen.

21. The microparticles of claim 19, wherein the entrapped species is an entrapped polynucleotide-containing species.

22. The microparticles of claim 19, wherein the entrapped species is an entrapped immunological adjuvant.

23. The microparticles of claim 1, further comprising a species adsorbed to the microparticles, wherein the adsorbed species is selected from an adsorbed second polynucleotide-containing species, an adsorbed polypeptide-containing species, an adsorbed polysaccharide-containing species, an adsorbed hormone, an adsorbed enzyme, and an adsorbed immunological adjuvant.

24. The microparticles of claim 23, wherein the additional species is an adsorbed polypeptide-containing antigen.

25. The microparticles of claim 23, wherein the additional species is an adsorbed second polynucleotide-containing species.

26. The microparticles of claim 23, wherein the additional species is an adsorbed immunological adjuvant.

27. The microparticles of claim 1, wherein the adsorbed first polynucleotide-containing species constitutes 10 to 30 percent of the total weight of the microparticles.

28. The microparticles of claim 1, wherein the adsorbed first polynucleotide-containing species constitutes 10 to 20 percent of the total weight of the microparticles.

29. The microparticles of claim 1, wherein the microparticles comprise 0.1 to 10 wt% cationic surfactant.

30. The microparticles of claim 1, wherein the microparticles comprise 0.5 to 2 wt% cationic surfactant.

31. The microparticles of claim 1, wherein the cationic surfactant is present during formation of the microparticles, and wherein no cationic surfactant removal step is conducted subsequent to formation of the microparticles.

32. The microparticles of claim 1, wherein a first portion of the cationic surfactant is bound to the polymer, wherein a second portion of the cationic surfactant forms a complex with the first polynucleotide-containing species, wherein the complex is adsorbed on the surface of the microparticles, and wherein the first surfactant portion and the second surfactant portion comprise the same surfactant species or different surfactant species.

33. The microparticles of claim 32, wherein the first and second surfactant portions comprise the same surfactant species.

34. A microparticle composition comprising the microparticles of any of claims 1-33 and a pharmaceutically acceptable excipient.

35. The microparticle composition of claim 34, further comprising an immunological adjuvant.

36. The microparticle composition of claim 35, wherein the immunological adjuvant is selected from CpG oligonucleotides, MF59, dsRNA, E. coli heat-labile toxins, phospholipids compounds, and aluminum salts.

37. The microparticle composition of claim 34, wherein the microparticle composition is an injectable composition.

38. A method of delivering a therapeutic amount of a polynucleotide-containing species to a host animal, comprising administering to the host animal the microparticle composition of claim 34.

39. A method of stimulating an immune response in a host animal, comprising administering to the host animal the microparticle composition of claim 34 in an amount effective to induce an immune response.

40. A method of treating a host animal having a pathogenic organism infection comprising administering to the animal a therapeutically effective amount of the microparticle composition of claim 34.

41. A method of immunizing a host animal against infection by a pathogenic organism comprising administering to the animal the microparticle composition of claim 34 in an amount effective to induce a protective response.

42. The method of claim 39, wherein the immune response comprises a cellular immune response.

43. The method of claim 39, wherein the immune response comprises a Th1 immune response.

44. The method of claim 39, wherein the immune response comprises a CTL immune response.

45. The method of claim 39, wherein the immune response is raised against a viral, bacterial, or parasitic infection.

46. The method of claim 39, wherein the host animal is a vertebrate animal.

47. The method of claim 39, wherein the host animal is a mammal.

48. The method of claim 39, wherein the host animal is a human.
49. Use of the microparticle composition of claim 34 for treatment of a disease.
50. Use of the microparticle composition of claim 34 for a vaccine.
51. Use of the microparticle composition of claim 34 for raising an immune response.
52. A method of producing the microparticles of any of claims 1-33, comprising: (a) forming a w/o/w emulsion comprising the polymer and the cationic surfactant; (b) removing the organic solvent from the emulsion, to form the microparticles; and (c) adsorbing the first polynucleotide-containing species to the microparticles.
53. The method of claim 52, wherein the microparticles are not subjected to a cationic surfactant removal step subsequent to microparticle formation.
54. Microparticles made according to the method of claim 52.
55. A microparticle composition comprising the microparticles of claim 54 and a pharmaceutically acceptable excipient.
56. A microparticle composition comprising (a) the microparticles of any of claims 1-33, and (b) additional microparticles comprising a biodegradable polymer and an immunological adjuvant adsorbed on the surface of the additional microparticles.
57. A microparticle composition comprising (a) the microparticles of any of claims 1-33, and (b) additional microparticles comprising a biodegradable polymer and an immunological adjuvant entrapped within the additional microparticles.
58. The microparticles of claim 14, wherein the RNA-virus-based plasmid is an alphavirus-based plasmid.

59. The microparticles of claim 58, wherein the alphavirus-based plasmid is a Sindbis-virus based plasmid.

60. The microparticles of claim 59, wherein the plasmid is pSINCP.

61. The microparticles of claim 13, wherein the plasmid is pCMV.

62. The microparticles of claim 12, wherein the DNA vector construct comprises a eukaryotic promoter 5' of viral cDNA which initiates within a cell the 5' to 3' synthesis of RNA from cDNA, wherein the RNA comprises a vector construct which autonomously amplifies in a cell, the vector construct expressing a heterologous nucleic acid sequence.

63. A microparticle composition comprising: (a) the microparticles of claim 1, wherein the biodegradable polymer is poly(lactide-co-glycolide) and wherein the first polynucleotide-containing species encodes a polypeptide-containing antigen; and (b) additional microparticles comprising poly(lactide-co-glycolide) and an immunological adjuvant, wherein the immunological adjuvant is adsorbed on the surface of the additional microparticles or is entrapped within the additional microparticles.

64. The microparticle composition of claim 63, further comprising an additional immunological adjuvant.

65. The microparticles of any of claims 1 and 3-33, wherein the cationic surfactant comprises cetyltrimethylammonium bromide.

66. The microparticles of any of claims 1-3 and 7-33, wherein the polymer comprises a poly(α -hydroxy acid) selected from poly(L-lactide), poly(D,L-lactide) and poly(lactide-co-glycolide).

67. The microparticles of any of claims 1-6 and 19-33, wherein the first polynucleotide-containing species is an immunological adjuvant.

68. The microparticles of any of claims 1-6 and 19-33, wherein the first polynucleotide-containing species is a vector construct that encodes a polypeptide-containing antigen.

69. The microparticles of claim 68, wherein the polypeptide-containing antigen is derived from a pathogenic organism or a tumor.

70. The microparticles of any of claims 1-26 and 29-33, wherein the adsorbed first polynucleotide-containing species constitutes 10 to 30 percent of the total weight of the microparticles.

71. The microparticles of any of claims 1-28 and 31-33, wherein the microparticles comprise 0.1 to 10 wt% cationic surfactant.